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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/590,430

06/18/2007

Andreas Obrebski

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EXAMINER

BOOTH, MICHAEL JOHN

ART UNIT

PAPER NUMBER

4158

MAIL DATE

DELIVERY MODE

11/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/590,430	Applicant(s) OBREBSKI, ANDREAS	
	Examiner MICHAEL J. BOOTH	Art Unit 4158	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06/18/2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/23/2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Abstract

- a. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

The abstract of the disclosure is objected to because it references to purported merits, such as the elimination of presbyopia. Correction is required. See MPEP § 608.01(b).

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

The disclosure is objected to because of the following informalities: Minor grammatical and/or spelling errors. For example, on page 6, last paragraph, "...may have an actuator and control can be effected..." and further "...the actuator--in

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particular..." The first error is grammatical and the second is a typo in which two hyphens are used, a comma is suggested (occurs again on page 22 second paragraph). Additional errors may exist and need to be addressed and corrected. Furthermore, when referencing a patent, make it clear that the reference is a patent, for example, on page 11, it states "from US-A-5,659,330" whereas it is suggested to state "US Patent 5,659,330" or similar format to cause no confusion between patent, publications, etc. Other instances occur throughout and need to be corrected. Furthermore, one element per reference number and vice versa. It is recommended that applicant use numbers to prevent confusion. For example, on page 24, element "pupil" is referenced (103) and further element "cornea" is referenced (103*). In the list of references, which does not belong in the specification, element "cornea" is referenced (108). All elements and reference characters need to be labeled consistently and appropriately.

Appropriate correction is required.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Flexible Artificial Lens Accommodated by means of Pressure or Electrical Conductivity.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 10, 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 5 recites the broad recitation at least 1.5 diopters, and the claim also recites at least 2.5 diopters and further at least 4 diopters which is the narrower statement of the range/limitation. In the present instance, claim 19 recites the broad recitation between 30 and 45 degrees

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Celsius, and the claim also recites between 35 and 40 degrees Celsius and further between 36 and 38 degrees Celsius which is the narrower statement of the range/limitation.

Regarding claims 5 and 19, the phrase "more preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Claims 5 and 19 claims a broad range and then further limits the range.

Regarding claim 10, it is unclear to the examiner what is being claimed. The examiner will interpret the claim as interchanging two media's.

Regarding claim 20, the phrase "in particular" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

The examiner has interpreted the claims using the broadest reasonable interpretation further ignoring the 'further limiting' terminology used.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-11, 13, 15-18, 21-22, 24, and 26-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Klopotek (US Patent 6,730,123; hereinafter Klopotek).

Concerning claims with 112 rejections as stated above. The examiner is unable to understand what the applicant is claiming for these respective claims. Thus, the examiner has taken the broadest reasonable interpretation. These claims rejected below as best understood. Basis for reasoning may be provided above under 112 rejection and further discussed below.

Concerning claim 1, 2, 6, 7:

Klopotek discloses an artificial lens (10) having two or more media, such as optical elements (14 & 16), that are flexible and come into direct contact with one another as lens elements, in an uptake container or optical chamber (18), thus forming a lens body. (column 2, lines 28-39). Such optical elements displaced relative to one another. Since Klopotek discloses increasing pressure in such chamber, it is inherent that the elements are fixed in space in the uptake container.

Concerning claim 3:

Klopotek discloses an artificial lens suitable for accommodation (abstract), wherein the lens is capable of changing shape and focusing.

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Concerning claim 4:

Klopotek discloses determining the refractive power prior to implantation, thus providing a pre-adjusted refractive power. (column 1, lines 22-33).

Concerning claim 5:

Klopotek discloses a dynamic range of refractive power at least 1.5 diopters. Since the cornea provides about 40 D and the lens provides about 20 D as disclosed by Klopotek. It is inherent that there is a range and that it is at least 1.5 diopters. (column 1, lines 10-21 and lines 45-59).

Concerning claim 8:

Klopotek discloses an artificial lens with an optical chamber therebetween two optical elements, further with a pump to create a pressure within the optical chamber, thus changing the size and/or shape due to these pressure changes between the media. (column 2, lines 28-39).

Concerning claim 9:

Klopotek discloses a control device for controlling the artificial lens, such as a gear pump. (column 2, lines 55-67).

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Concerning claim 10:

It is unclear what is being claimed. Thus, the examiner will interpret it as two media, flexible in shape, made of material such as a hydrogel, furthermore where these materials cannot be mixed. Since the materials are separate, they are not mixed or interchanged. Where mixed or interchanged, an example (for understanding of the terminology used and not comparison) is adding sugar to water.

Concerning claims 11 and 21:

Klopotek discloses at least one boundary of the uptake container (18) having at least one arched contour, such as shown in FIG. 1A. Klopotek further discloses the medium, flexible in shape, displaced in direction when accommodated, such that at least one optical element's curvature is altered. Since the optical elements are accommodating, the lens will adjust its curvature in response to this.

Concerning claims 13 and 15:

Klopotek discloses one or more boundaries of an optical chamber or uptake container made of flexible material, at least in regions. (abstract). Such boundaries exist on the material, and the material is flexible, thus the boundaries are flexible. Klopotek further discloses a medium that is flexible and applied to at least one surface. Such as an optical element applied to another optical element.

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Concerning claim 16:

Klopotek discloses media, such as an optical element, formed as a type of a gel, such as a hydrogel. (column 10, lines 27-33).

Concerning claim 17:

Klopotek discloses media made in the form of one or more drops, such as an onion-like structure, would be the same structure as a drop. (column 2, lines 1-6).

Concerning claim 18:

Klopotek discloses media in claim 16 above, and further discloses two optical elements, both being made of the same material, thus, it is inherent that both media would have the same or approximately the same density.

Concerning claim 22:

Klopotek discloses a means for changing the interface(s), such as a gear pump, wherein gears have a center and are disposed annularly around said center or opening where the gears are housed. (FIG. 2).

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Concerning claim 24:

The Examiner recognizes claim 24 as a "product-by-process" claim. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process (*In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966).

Klopotek discloses all of the structural limitations of the artificial lens wherein the lens is flexible in shaped as disclosed previously.

Concerning claims 26-29:

Klopotek discloses a means for changing the interface of a media that is flexible in shape, such means designed to produce a pressure on at least one of the media that is flexible in shape, and pressed by a medium in a preferred direction. Such that the optical fluid therebetween the two optical elements having an increase in pressure due to a mechanical gear pump, where gear pump is considered a cylinder device due to its housing. Such pressure would cause optical fluid to compress against the optical elements and thus change the shape of the optical elements and its surrounding structures attached thereof. (column 2).

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Concerning claim 30:

Klopotek discloses a control device for controlling the artificial lens, such as a gear pump, with a controllable membrane, such as the gears. (column 2, lines 55-67).

Concerning claims 31 and 32:

Klopotek discloses the optical elements being fastened or fused (column 4, lines 53-61) together. The two components formed as a base and cover, whereas the base and cover are fused together. The points of contact that create the fusing considered the coatings of the optical elements which are in the form of a geometric configuration of the regions of the uptake container of optical chamber to allow the elements to fuse in the shape desired.

Concerning claims 33 and 34:

Klopotek discloses an artificial lens with a means for stabilizing the surface structure, such as with a haptic (36a) as shown in Fig. 1A. Furthermore, said stabilizing means provided between two optical elements (14 & 16) as shown in Fig. 1A. (column 2, lines 40-43).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12, 14, 19, 20, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klopotek as applied to claims 1, 2, 18, 22 and 24 above, and further in view of Esch (US Patent 7,122,053; hereinafter Esch).

Concerning claims 12 and 14:

Klopotek fails to explicitly disclose an artificial lens made transparent in one or more boundaries or media. However, Esch discloses the boundaries or media of a lens being transparent. (column 2, lines 1-6). Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Klopotek to have lens made transparent. There is motivation to combine the two references as they are in the same field of endeavor.

Concerning claim 19:

Klopotek fails to disclose the temperature range that the media may be. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to use a material that would have a temperature range that can withstand that of the human body in the area of approximately 37 degrees Celsius give or take depending on whether or not a person is ill or not.

Concerning claim 20:

Klopotek fails to disclose the use of different optical properties such as refractive numbers. However, Esch discloses use of different indices of refraction. (column 3, lines 45-57). Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Klopotek with different indices of refraction.

Concerning claim 23:

Klopotek fails to disclose the size of the clear opening. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Klopotek with an opening to correspond to at least the maximum pupil diameter for the eye to allow proper focusing and function of the lens.

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Concerning claim 25:

Klopotek fails to disclose specifically different electrical conductivity of the mediums and having electrodes. However, Esch discloses use of different optical properties such as indices of refraction. Klopotek does disclose a magnetic field generator, or electric field generator or photons. (column 2, lines 15-20). Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Klopotek with Esch's different optical properties to have different electrical conductivity on the mediums further with an electrode to allow proper use of the magnetic field generator as disclosed by Klopotek to aid in accommodation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL J. BOOTH whose telephone number is (571)270-7027. The examiner can normally be reached on Monday thru Thursday, 8:00am - 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on (571)272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

11/05/2008

/M. J. B./

Examiner, Art Unit 4158

/G. J./

Supervisory Patent Examiner

Art Unit 4158